EXHIBIT 12

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

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d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[106]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether they will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[107]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[108] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[109]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances should implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant

[106] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[107] *Id*.

[108] *See, e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[109] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical 1st step to ensures a potential customer has a business plan consistent with compliance to the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer
        - Identify any affiliation with pain management doctors
        - Review percentage of controlled substance business
        - Identify any other distributors providing control substances
        - Review the percentage of cash payments and insurance payments
        - Review of pharmacy utilization reports
        - On-site inspection of customer
        - Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when the order is identified by the system. A system that establishes thresholds which are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. A suspicious order system to be effective contains many components which should include, but not limited to, the following:
    - Customer Types – Customers should be placed in into customer types based on the business activity identified through the due diligence documentation.

- Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
- Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size in a minimum of three groups, based on the volume of their ordering history identified through the due diligence documentation.
- Drug Types – A suspicious order system to be effective should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
- Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the registrant's knowledge of the customers business model, due diligence investigation, comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of customer for a period of at least 12 months.
- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to insure it is consistent with legitimate population consumption. Customers who identify an activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the ordering pattern deviates from established levels or what would be normal for another similarly situated customer this could indicate potential diversion.
- Pattern of Orders - Are controlled substances ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – The frequency of orders for controlled substances increasing disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify large volume of controlled substances

consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. As orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence should include the following:

    - An established procedure and criteria for setting threshold quantities.
    - The person or department who is responsible for approving threshold quantities is specifically identified.
    - A procedure for adjusting threshold quantities that requires thorough review and documentation.
    - Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:
        - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided
        - Analysis of the patient population serviced by the customer
        - Analysis of the physician population serviced by the customer
        - Analysis of the results of an adequate on-site customer review program
        - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes
    - Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
    - Sales role (if any) in the compliance review program must be appropriately managed.
    - On-site review includes the acquisition and review of utilization report.
    - Request for threshold changes necessitates an on-site review.
    - The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
    - Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.

- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

utilized by one or more of the defendants. These methodologies are identified in the McCann Report as "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[110]

A. Methodology: Maximum Monthly, Trailing 6 Month Threshold

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 46)	[redacted]	
Cardinal (p. 91)		
McKesson Corporation (p. 136)		
CVS (p. 181)		
Walgreens (p. 236)		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 676)	[redacted]	
Cardinal (p. 721)		
McKesson Corporation (p. 766)		
CVS (p. 811)		
Walgreens (p. 236)		

[110] I utilized these Defendants: Cardinal Health, AmerisourceBergen Drug, McKesson, Walgreens, and CVS as they constitute a significant majority of the opioid pills delivered into CT1 according to the data described in the Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, pp. 3775 and 3845.

B. Methodology: 2x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[111]	[redacted]	
Cardinal[112]		
McKesson Corporation[113]		
CVS[114]		
Walgreens[115]		

Summit County: 1996-2018

Distributor
AmerisourceBergen Drug[116]
Cardinal[117]
McKesson Corporation[118]
CVS[119]
Walgreens[120]

[111] *Id*. at 55.

[112] *Id*. at 100.

[113] *Id*. at 145.

[114] *Id*. at 190.

[115] *Id*. at 235.

[116] *Id*. at 685.

[117] *Id*. at 730.

[118] *Id*. at 775.

[119] *Id*. at 20.

[120] *Id*. at 865.

C. Methodology: Extraordinary Order Method - 3x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[121]	[redacted]	
Cardinal[122]		
McKesson Corporation[123]		
CVS[124]		
Walgreens[125]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[126]	[redacted]	
Cardinal[127]		
McKesson Corporation[128]		
CVS[129]		

[121] *Id*. at 64.

[122] *Id*. at 109.

[123] *Id*. at 154.

[124] *Id*. at 199.

[125] *Id*. at 244.

[126] *Id*. at 694.

[127] *Id*. at 739.

[128] *Id*. at 784.

[129] *Id*. at 829.

Walgreens[130]	[redacted]

D. Methodology: Maximum 8,000 Dosage Units Monthly

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[131]	[redacted]	
Cardinal[132]		
McKesson Corporation[133]		
CVS[134]		
Walgreens[135]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[136]	[redacted]	
Cardinal[137]		
McKesson Corporation[138]		

[130] *Id*. at 874.

[131] *Id*. at 73.

[132] *Id*. at 118.

[133] *Id*. at 163.

[134] *Id*. at 208.

[135] *Id*. at 253.

[136] *Id*. at 703.

[137] *Id*. at 748.

[138] *Id*. at 793.

CVS[139]	[redacted]
Walgreens[140]	

E. Methodology: Maximum Daily Dosage Units

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[141]	[redacted]	
Cardinal[142]		
McKesson Corporation[143]		
CVS[144]		
Walgreens[145]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[146]	[redacted]	
Cardinal[147]		

[139] *Id*. at 838.

[140] *Id*. at 883.

[141] *Id*. at 82.

[142] *Id*. at 127.

[143] *Id*. at 172.

[144] *Id*. at 217.

[145] *Id*. at 262.

[146] *Id*. at 712.

[147] *Id*. at 757.

McKesson Corporation[148]	[redacted]
CVS[149]	
Walgreens[150]	

I have been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[151] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[152] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.

IV. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

[148] *Id*. at 802.

[149] *Id*. at 847.

[150] *Id*. at 892.

[151] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

[152] This approach does not take into consideration unusual pattern or frequency.

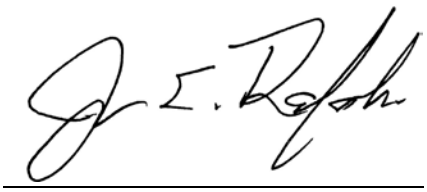
respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.[908]

5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.[909] For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



James E. Rafalski

Date: April 15, 2019

[908] *See* Deposition of James Doroz at 53; 118; 251. *See* also Thomas Udicious Tr. at 19; 44.

[909] *See* James Doroz Tr. at 221.